September 15, 2021

Vascular Solutions, Inc.
Sara Coon
Sr. R.A. Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K052232
Trade/Device Name: Pronto V3 Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Sara Coon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 28, 2005. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:09:58 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052232
Pronto V3™ Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: II
Product Code: DXE
Dated: August 16, 2005
Received: August 17, 2005

Dear Ms. Coon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K052232

Device Name: Vascular Solutions Pronto V3™ Extraction Catheter

Indications for Use:

The Pronto V3 Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052232

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K052232

SEP 2 8 2005

Appendix A: Summary of Safety and Effectiveness

Common/Usual Name: Embolectomy Catheter

Product Trade Name: Pronto V3™ Extraction Catheter

Classification Name: Unclassified
Product Code, DXE

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4250 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:

The Pronto V3 extraction catheter is a dual lumen catheter with related accessories. The extraction lumen allows for the aspiration and removal of embolic material (thrombus/debris) using the included syringe, extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate atraumatic advancement of the catheter into the blood vessel and maximize extraction of emboli/thrombi through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. The catheter is a monorail design with a distal flexible region with stiffness along the shaft tapering to a stiff proximal region. The distal segment of the catheter is coated with a hydrophilic coating to lubricate the catheter for ease of insertion. The catheter has an approximate outer diameter of 0.065 inches, allowing delivery through standard 6Fr. guide catheters. The smaller wire lumen of the catheter is able to accommodate guide wires that are ≤ 0.014" in diameter. The catheter will be available in working lengths of 40 to 145 cm with the length changes being made in the proximal rail section. The proximal end of the

catheter incorporates a standard luer adapter to facilitate the attachment of the catheter to the included extension line, stopcock, and syringe. A 74 micrometer filter basket (not identified in the schematic below) is included for assistance in filtering the blood removed during the procedure for laboratory analysis of thrombus.

Intended Use:

The Pronto V3 Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial systems.

Summary of Non-Clinical Testing:

Testing conducted included assessments of the design verification of the Pronto V3 Extraction Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Pronto V3 Extraction Catheter for its intended use.

Summary of Clinical Testing:

No clinical evaluations of this product have been conducted.

Predicate Devices:

The Pronto V3 Extraction Catheter is similar in intended use to the Vascular Solutions, Inc. Pronto Extraction Catheter and the Medtronic Export™ Aspiration Catheter.

Conclusions:

The Pronto V3 Extraction Catheter is substantially equivalent to the Pronto Extraction Catheter and the Export Aspiration Catheter. The testing performed confirms that the Pronto V3 Extraction Catheter will perform as intended.

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Donna R. Lachman

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